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Amend
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29. (New) A package which is stored in air and which comprises
- (a) a sealed container, and
 - (b) within the sealed container, a respiring biological material and a packaging atmosphere around the biological material
- the sealed container including one or more permeable control sections which provide at least the principal pathway for oxygen and carbon dioxide to enter or leave the packaging atmosphere, at least one said permeable control section being a gas-permeable membrane as defined in claim 20.

REMARKS

Amendments

In the specification.

The following comments are made on the numbered amendments to the specification.

1. The amendments to this paragraph note that this application is a continuation of Serial No. 08/759,602, and that the grandparent application Serial No. 08/453,108 has been abandoned.
2. The amendment to this paragraph is the insertion at the end of the paragraph, after "... the second heating cycle." on page 3, line 15 of the specification, of additional information about the conventional way in which the values of T_o and T_p are measured. The same amendment was made to the parent application.
3. The amendment to this paragraph is the replacement of the words "is now" on page 5, line 12, by the words -- was previously -- .

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Clarke et al

Parent Application

Serial No. Not Yet Known

Group Art Unit: 1772

Filing Date: Herewith

Examiner: Dye, R.L.

Title: Gas-permeable Membrane

Continuation of Serial No.: 08/759,602 filed December 5, 1996

Assistant Commissioner for Patents

Washington, DC 20231

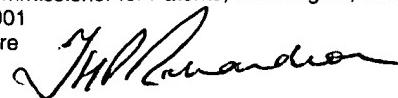
Version of Amended Claims with Markings to show Changes requested by the
accompanying Preliminary Amendment, in accordance with 37 CFR 1.121(c)(1)(ii)

This paper sets out a version of each of the claims rewritten as requested by the accompanying Amendment under 37 CFR 1.312 (but not the claims which were unchanged or the claims which were added), marked up to show all the changes relative to the previous version of the claim. In this version,

- (i) a parenthetical expression (which is the same as the parenthetical expression in the clean version of claims set out in the Preliminary Amendment) follows the claim number and indicates the status of the claim as amended, and
- (ii) the changes are shown by brackets (for deleted matter) and underlining (for added matter).

EXPRESS MAIL CERTIFICATION UNDER 37 CFR 1.10

I hereby certify that this paper is being deposited with the "Express Mail Post Office to Addressee" service of the United States Postal Service on the date indicated below and is addressed to Assistant Commissioner for Patents, Washington, D.C. 20231. Express Mail mailing label No. *EF 278801101 Date of Deposit Oct. 12, 2001
Typed name of person signing this certificate: T. H. P. Richardson Signature



1. (Amended) A gas-permeable membrane which is useful in the packaging of respiring biological materials and which comprises

- (a) a microporous polymeric film comprising a network of interconnected pores such that gases can pass through the film, and
- (b) a polymeric coating on the microporous film,

wherein

- (1) the pores in the microporous film have an average pore size of less than 0.24 micron; and
- (2) the microporous film was prepared by a process comprising the steps of
 - (A) preparing a uniform mixture comprising the polymeric matrix material in the form of a powder, the filler, and a processing oil;
 - (B) extruding the mixture as a continuous sheet;
 - (C) forwarding the continuous sheet, without drawing, to a pair of heated calender rolls;
 - (D) passing the continuous sheet through the calender rolls to form a sheet of lesser thickness;
 - (E) passing the sheet from step (D) to a first extraction zone in which to the processing oil is substantially removed by extraction with an organic extraction liquid which is a good solvent for the processing oil, a poor solvent for the polymeric matrix material, and more volatile than the processing oil;
 - (F) passing the sheet from step (E) to a second extraction zone in which the organic extraction liquid is substantially removed by steam or water or both; and
 - (G) passing the sheet from step (F) through a forced air dryer to remove residual water and organic extraction liquid; and
- (3) the polymeric coating has a thickness such [the polymeric coating changing the permeability of the microporous film so] that the membrane
 - (i) has a P₁₀ ratio, over at least one 10°C range between -5 and 15°C, of at least 1.3;

- (ii) has an oxygen permeability (OTR), at all temperatures between 20° and 25°C, of at least 775,000 ml/m².atm.24 hrs (50,000 cc/100 inch².atm.24 hrs; and
- (iii) has a CO₂/O₂ permeability ratio(R) of at least 1.5; the P₁₀, OTR and R values being measured at a pressure of 0.035 kg/cm² (0.5 psi)

2. A membrane according to claim 1 wherein [which has at least one of the following characteristics

- (1) the microporous film has an average pore size of less than 0.24 micron;
- (2) the microporous film has a tear strength of at least 30g;
- (3) the microporous film has a Sheffield Smoothness of at least 30;
- (4)]

the microporous film comprises a polymeric matrix selected from the group consisting of [comprising]

- (i) an essentially linear ultrahigh molecular weight polyethylene having an intrinsic [intrinsic] viscosity of at least 18 deciliters/g and [;
- (5) the microporous film comprises a polymeric matrix comprising]
- (ii) an essentially linear ultrahigh molecular weight polypropylene having an intrinsic viscosity of at least 6 deciliters/g. [;
- (6) the microporous film comprises a finely divided, particulate, substantially insoluble filler which is distributed throughout the film;
- (7) the coating weight of the coating polymer is 1.7 to 2.9 g/m²; and
- (8) the coating polymer is a crystalline polymer having a T_p of -5° to 15°C.]

3. (Amended) A membrane according to claim 1 wherein at least 70% of the pores in the microporous film have a pore size of less than 0.24 micron. [which has a P₁₀ ratio between 0 and 10°C of at least 2.6, the P₁₀ being measured at a pressure of 0.035 kg/cm² (0.5 psi).]

4. (Amended) A membrane according to claim 1 wherein at least 90% of the pores in the microporous film have a pore size of less than 0.24 micron. [2 which has a P_{10} ratio between 0 and 10°C of at least 2.6, the P_{10} being measured at a pressure of 0.035 kg/cm² (0.5 psi).]

5. (Amended) A membrane according to claim 1 wherein substantially 100% of the falls in the microporous film have a pore size of less than 0.24 micron. [which has [a P_{10} ratio, over at least one 10°C range between -5°C and 15°C, of at least 2.6, an OTR at all temperatures bewteen 20°C and 25°C of at least 1,550,000 ml/m².atm.24 hrs (100,000 cc/inch².atm.24 hrs, and an R ratio of at least 2.5, the P_{10} , OTR and R values being measured at a pressure of 0.035 kg/cm² (0.5 psi).

[5.] 6. (Amended) A membrane according to claim [2] 1 wherein at least 80% of the pores in the microporous film have a pore size less than 0.15 micron and at least 70% of the pores have a pore size less than 0.11 micron. [which has a P_{10} ratio, over at least one 10°C range between -5°C and 15°C, of at least 2.6, an OTR at all temperatures bewteen 20°C and 25°C of at least 1,550,000 ml/m².atm.24 hrs (100,000 cc/inch².atm.24 hrs, and an R ratio of at least 2.5, the P_{10} , OTR and R values being measured at a pressure of 0.035 kg/cm² (0.5 psi).]

7. (Amended) A membrane according to claim 1[wherein at least 90% of the pores have a pore size less than 0.24 micron, and] which has [a P_{10} ratio, over at least one 10°C range between -5 and 15°C of at least 1.3,] an OTR of at least 1,550,000 [775,000 to 3,100,000] ml/m² atm.24 hrs (100,000 [50,000 to 200,000] cc/100 inch².atm 24 hrs), and an R ratio of at least 2, the [P₁₀,]OTR and R values being measured at a pressure of 0.7 kg/cm² (10 psi).

8. (Amended) A membrane according to claim 7 which has [at least one of the following characteristics

- (1) it has a P_{10} ratio of at least 1.3 over at least one 10°C temperature range between 0° and 15°C;

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- (2) it has a P_{10} ratio of at least 2 over at least one 10°C temperature range between 0° and 15°C;
 - (3) it has a P_{10} ratio of at least 2.5 over at least one 10°C temperature range between 0° and 15°C;
 - (4) it has an OTR of at least 1,550,000 ml/m².atm.24 hrs (100,000 cc/100 inch².atm.24 hrs);
 - (5) it has] an OTR of at least 2,325,000 ml/m².atm.24 hrs (150,000 cc/100 inch².atm.24 hrs),[;
 - (6) it has an OTR of 775,000 to 3,100,000 ml/m².atm.24 hrs (50,000 to 200,000 cc/100 inch².atm.24 hrs) and an R value of more than (3.8 - 0.00000045P), where P is the OTR in ml/m².atm.24 hrs;
 - (7) it has an OTR of 775,000 to 3,100,000 ml/m².atm.24 hrs (50,000 to 200,000 cc/100 inch².atm.24 hrs) and an R value of (3.8 - 0.0000045P) to (7.4 - 0.000016P), where P is the OTR in ml/m².atm.24 hrs;
 - (8) it has an OTR of 775,000 to 3,100,000 ml/m².atm.24 hrs (50,000 to 200,000 cc/100 inch².atm.24 hrs) and an R value of (3.8 - 0.0000045P) to (5.6 - 0.000084PI), where P is the OTR in ml/m².atm.24 hrs;
 - (9) it has an R ratio of at least 2.5; and
 - (10) it has an R ratio of at least 3.

the P_{10} , OTR and R values being] measured at a pressure of 0.07 kg/cm² (10 psi).

Claims 9 and 10 canceled

11. (Amended) A membrane according to claim 1 [7] wherein the coating polymer [has at least one of the following characteristics:

- (1) it is a crystalline polymer having a T_p of -5 to 40°C and a ΔH of at least 5 J/g;
- (2) it is a crystalline polymer having a T_p of 0 to 15°C and a ΔH of at least 20 J/g;
- (3) it is a side chain crystalline polymer;

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- (4) it is a side chain crystalline polymer in which $T_p - T_o$ is less than 10°C;
 - (5) it is a side chain crystalline polymer prepared by copolymerizing (i) at least one n-alkyl acrylate or methacrylate in which the n-alkyl group contains at least 12 carbon atoms and (ii) one or more comonomers selected from acrylic acid, methacrylic acid, and esters of acrylic or methacrylic acid in which the esterifying group contains less than 10 carbon atoms;
 - (6) it] is [cis-polybutadiene, poly(4-methylpentene),]polydimethyl siloxane [, or ethylene-propylene rubber; and
 - (7) it has been crosslinked].

12. (Amended) A membrane according to claim 1 [8] wherein the coating polymer [has at least one of the following characteristics:

- (1) it is a crystalline polymer having a T_p of -5 to 40°C and a ΔH of at least 5 J/g;
- (2) it is a crystalline polymer having a T_p of 0 to 15°C and a ΔH of at least 20 J/g;
- (3) it is a side chain crystalline polymer;
- (4) it is a side chain crystalline polymer in which $T_p - T_o$ is less than 10°C;
- (5) it is a side chain crystalline polymer prepared by copolymerizing (i) at least one n-alkyl acrylate or methacrylate in which the n-alkyl group contains at least 12 carbon atoms and (ii) one or more comonomers selected from acrylic acid, methacrylic acid, and esters of acrylic or methacrylic acid in which the esterifying group contains less than 10 carbon atoms;
- (6) it] is cis-polybutadiene, poly(4-methylpentene)[, polydimethyl siloxane,] or ethylene-propylene rubber[; and
- (7) it has been crosslinked].

13. (Amended) A membrane according to claim 1 [9] wherein the coating polymer [has at least one of the following characteristics:

- (1) it is a crystalline polymer having a T_p of -5 to 40°C and a ΔH of at least 5 J/g;

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- (2) it is a crystalline polymer having a T_p of 0 to 15°C and a ΔH of at least 20 J/g;
 - (3) it is a side chain crystalline polymer;
 - (4) it is a side chain crystalline polymer in which T_p-T_o is less than 10°C;
 - (5) it is a side chain crystalline polymer prepared by copolymerizing (i) at least one n-alkyl acrylate or methacrylate in which the n-alkyl group contains at least 12 carbon atoms and (ii) one or more comonomers selected from acrylic acid, methacrylic acid, and esters of acrylic or methacrylic acid in which the esterifying group contains less than 10 carbon atoms;
 - (6) it is cis-polybutadiene, poly(4-methylpentene), polydimethyl siloxane, or ethylene-propylene rubber; and
 - (7) it has been crosslinked.

14. (Unchanged)

15. (Unchanged)

16. (Amended) A package which is stored in air and which comprises

- (a) a sealed container, and
- (b) within the sealed container, a respiring biological material and a packaging atmosphere around the biological material,

the sealed container including one or more permeable control sections which provide at least the principal pathway [substantially the only pathways] for oxygen and carbon dioxide to enter or leave the packaging atmosphere, at least one said permeable control section being a gas-permeable membrane as defined in claim 1.

Claims 17-19 canceled

Respectfully submitted,



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4. The amendment to this paragraph replaces the words "substantially the only pathways" on page 6, line 4, by the words -- at least the principal pathway, and optionally substantially the only pathway --. Basis for this amendment will be found on page 2, lines 22-25.
5. The amendment to this paragraph corrects and amplifies the information given about the preferred characteristics of the microporous film. The same amendment was made to the parent application. As noted in the parent application, basis for these amendments will be found in U.S. Patent No. 4,937,115, which is incorporated by reference in this and the parent application on page 8, lines 3-4. As the Examiner will see, the information inserted into the specification is disclosed at column 7, line 52, to column 8, line 12, of U.S. Patent No. 4,937,115. It should also be noted that there is an error (now corrected) on page 7, line 30, of the original specification, since the films in question are not made by methods which involve stretching. On the contrary, stretching should be avoided (see for example, column 2, line 53, and column 7, line 62, of U.S. Patent No. 4,937,115), because it results in pores of less uniform size. A copy of U.S. Patent No. 4,937,115 is attached.
6. The amendment to this paragraph is the deletion of the last sentence (" The ΔH values... respectively."), on page 15, lines 21-22.
7. The amendment to this paragraph is the deletion of the last sentence (" The P_{10} ratios... increasing P_{10} ratios.") on page 18, lines 15-16.
- 8.-13. The amendments to the Tables, as set out above, are the insertion of asterisks before the numbers of the Examples which are comparative examples, because the membranes in question have oxygen permeabilities which are below the minimum specified in the revised claims.
14. and 15. The amendments to this paragraph and to Table 6, as set out above, are the correction of the units in which the temperatures are expressed from " $^{\circ}F$ " to -- $^{\circ}C$ --.

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16. The amendment to this paragraph is the replacement of "in" by --, --, thus correcting a typographical error.

In the claims.

The amendments made to claims 1-19 as filed will be apparent from the attached Marked-up Version of the Amended Claims, and the content of the new claims 20-29 will be apparent from the new claims set out above. The following additional comments are made for the assistance of the Examiner.

General

The amended claims contained two independent claims, Claim 1 and claim 20. Amended Claim 1 requires that the microporous film was prepared by steps (A) - (I) as set out in the claim. New claim 20 requires not only that the microporous film has an average for size of less than 0.24 micron, but also that

at least 70% of pores have a pore size of less than 0.24 micron,

less than 20% of the pores have a pore size less than 0.014 micron and

less than 20% of pores have a pore size greater than 0.13 micron.

The requirements summarized above provide a sharp line of distinction over the Antoon reference (U.S. Patent No. 5, 160, 768) which was relied upon by the Examiner to reject the original claims in the parent application. Antoon discloses coated membranes comprising a specific type of microporous film and a coating thereon of a cured silicone elastomer. In the parent application, the claims were restricted to the use of crystalline polymers and the Examiner withdrew the rejection over Antoon. The independent claims in this continuation application, however, include membranes in which the coating on the microporous film is composed of a cured silicone elastomer.

The specific type of microporous film disclosed by Antoon is a uniaxially or biaxially oriented olefin (e.g. polypropylene or polyethylene) film containing 40-75% of a

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filler (e.g. calcium carbonate). As noted in column 4, lines 48-59, of Antoon, the uniaxial or biaxial orientation of the filled olefin film causes the polymer to pull away from the filler, thus creating voids and pores in the film matrix. The random nature of the process used to manufacture Antoon's microporous films necessarily results in films having a wide range of pore sizes. In Applicants' invention, by contrast, the microporous film preferably has a relatively narrow range of pore sizes (see for example page 7, lines 29-30). This preferred feature of Applicants' invention has been made an essential feature of the amended claims of this continuation application, thus distinguishing them from Antoon. In amended Claim 1, this feature is incorporated by specifying that the microporous film was prepared by a process which inherently produces a narrow range of pore sizes (see page 7, line 29 - page 8, line 5, as amended). In new independent claim 20, this feature is incorporated directly, by narrowly defining the permissible percentages of pore sizes, both at the upper end and at the lower end of the range of sizes. Dependent claims 3-6 and 21-23 are limited to yet narrower classes of microporous film, further distinguishing from Antoon.

Basis for the amended claims 1-19 will be apparent from the attached Marked-up Version of Amended Claims and the following comments.

Claim 1

lines 1-2 "useful in the packaging of respiring biological materials"
page 14, lines 24-26

lines 3-4 "network of interconnected pores"
page 6, lines 18-20

lines 7-8 "average pore size less than 0.24 micron"
page 6, lines 20-21

lines 9-26 process for preparing the microporous film
page 7, line 29-page 8, line 5, as explained in detail above in connection with the amendment 5. to the specification.

Claims 3-5 at least 70%, or at least 90 %, or substantially 100%, of the pores have a pore size of less than 0.24 micron
page 6, lines 22-23

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- Claim 6 at least 80% of the pores have a pore size less than 0.15 micron and at least 70% have a pore size less than 0.11 micron
page 6, lines 23-25
- Claim 7 OTR of at least 1,550, 000
Claim 5
- Claim 16 at least the principal pathway
page 2, lines 22-25

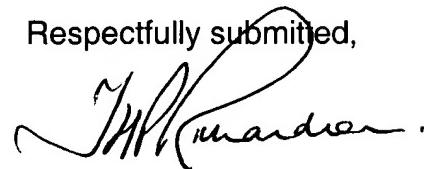
Basis for the new claims 20-29 will be apparent from the following comments.

- Claims 20-23 See Claim 1 and page 6, lines 20-29
- Claims 24-25 See amended claims 7 and 8
- Claims 26-28 See claims 11-13
- Claim 29 see amended Claim 16

CONCLUSION

It is believed that this application is now in condition for allowance, and such action at an early date is earnestly requested. If, however, there are any outstanding issues, the Examiner is asked to call the undersigned in the hope that they can be resolved by a telephone interview.

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